Jeffrey Shuren, M.D., J.D.,
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Food and Drug Administration
10903 New Hampshire Ave
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December 4, 2018

Questions RE: FDA's Rejection of the Cancer Association Found in the National Toxicology Program Radiofrequency Cell Phone Research Studies

Dear Dr. Jeffrey Shuren;

As you are aware, the National Toxicology Program (NTP)/National Institutes of Environmental Health Sciences released their final reports on their $30 million animal study on long-term exposure to wireless radiofrequency electromagnetic (RF-EMF) radiation. They found statistically significant increases in DNA damage, heart damage, malignant glioma tumors of the brain, and malignant schwannomas of the heart. The increased incidence of heart tumors were considered by the expert peer-reviewers and staff of the NTP to demonstrate "clear evidence of carcinogenic activity" of modulated cell phone radiofrequency radiation. Similarly, studies by the Ramazzini Institute of RF-EMF at levels below FCC limits (Falcioni 2018) found increases in malignant schwannomas of the heart in exposed rats.

importantly, these animal study findings support published case control studies in humans which found increases in tumors of the same types- schwannomas and gliomas. In 2011, RF-EMF was classified as a Group 2B possible carcinogen by the World Health Organization's International Agency for Research on Cancer based on published research that found tumor increases in humans using cell phones long term. Now, in 2018, these animal studies substantially strengthen the scientific evidence that RF-EMF causes cancer, and scientists have concluded that there is now sufficient evidence to classify RF-EMF as a human carcinogen (Hardell and Carlberg, 2017, Peleg et al., 2018, Miller et al., 2018).

However in response to the NTP final reports, the FDA stated, "After reviewing the study, we disagree, however, with the conclusions of their final report regarding "clear evidence" of carcinogenic activity in rodents exposed to radiofrequency energy."

We ask these questions to the FDA:

1.Please provide copies of any technical comments that substantiate the FDA's conclusions that NTP study did not find "clear evidence" of carcinogenicity for RF-EMF.

2. Specifically what are the FDA's conclusions regarding the schwannomas of the heart in male rats, the brain gliomas in the male rats, the DNA damage, and the cardiomyopathy of the heart?

3. The FDA states that "Based on our ongoing evaluation of this issue, the totality of the available scientific evidence continues to not support adverse health effects in humans caused by exposures at or under the current radiofrequency energy exposure limits." Please provide the documentation of the FDA's "ongoing evaluation." We respectfully request that you indicate the specific review process through which such an evaluation was undertaken and share with us the FDA evaluation which we expect is in a report with citations for the research that was analyzed.

4. The FDA stated of the March 2018 peer review "The FDA was not a participant in that process, but was invited to observe the panel discussions, which included an assessment of the study methods and data by a panel of 15 peer reviewers to determine the basis of evidence for the final report." However two FDA officials came to the National Toxicology Program's peer review of the study and had an opportunity to speak and offer comments. Yet the FDA did not provide official comments on the study at that time. FDA scientists did agree with the design of the NTP studies, which were presented to the Radiofrequency Interagency work group in 2003. Did the FDA ever share their disagreements with the NTP at any time- before and/or after the peer review? If so, please provide the comments of the FDA to the NTP.

5. The FDA nominated cell phone radiation emitted from wireless communication devices to the NTP in 1999 and specifically stated that "animal experiments are crucial because meaningful data will not be available from epidemiological studies for many years due to the long latency period between exposure to a carcinogen and the diagnosis of a tumor," and that such studies would "provide the basis to assess the risk to human health."

6. Did the FDA inform the NIH/NTP at any time over the last twenty years since this nomination that animal research would not be sufficient to determine risk to public health from cell phone radiation? Further, please clarify if it is now the FDA's position that animal research is no longer relevant to human health? If this is the case, will animal studies no longer be used to assess cancer risks from food contaminants and how does the FDA propose to treat pharmacological testing of animals in support of pharmaceutical registration process?

7. The FDA states that, "We believe the existing safety limits for cell phones remain acceptable for protecting the public health." However the FCC limits on allowable radiofrequency exposures are based on the assumption that only thermal RF levels can cause harm. The NTP studies were carefully controlled to minimize any potential thermal effects of RF on exposed animals, yet cancers and other adverse health effects were found at these nonthermal levels. Please provide the FDA's scientific documentation that evaluates the current FCC limits in light of the NTP and Ramazzini studies to understand how the FDA can state FCC limits are adequate to protect human health.

8. Kindly provide copies of FDA submitted recommendations, reports or opinions to the FCC regarding the radiofrequency human exposure exposure limits and policies? This could be either to the FCC Docket's 13-84, 03-137 or directly to the agency.

9. Will the FDA be performing a quantitative risk assessment? If so, please provide a timeline. If not please explain how and why that decision was made.

Sincerely,

Ron Melnick PhD
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